RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1- 16 are now pending and are presented for reconsideration.

B. Rejection under 35 U.S.C. § 102

The Action maintains the assertion that claim 1 is anticipated under 35 U.S.C. § 102(b) by Fry *et al.* (U.S. Patent 5,631,152). Applicants traverse as the Action has again failed to make a *prima facie* case for anticipation. The instant Action fails to identify where Fry *et al.* explicitly or implicitly teach all of the elements of claim 1. In particular, Fry does not teach the use of a multiple bud-inducing media in a method for making transgenic wheat. For example, the Action states that Fry "disclose a method for producing transgenic wheat comprising culturing explants, introducing exogenous DNA *via* bombardment, transferring cells from a first media to a second media to induce elongation of buds into shoots, harvesting and transferring shoots to a culture medium that promotes root development and culturing transferred shoots to produce plants". However, claim 1 of the current invention recites that the explant is to be cultured "in a first ***multiple*** bud inducing media suitable for inducing production of a plurality of buds from at least one of said meristems" (emphasis added). As explained in the specification, a multiple bud inducing media "generates multiple plants from a single explant" [0028].

Fry do not teach regeneration of an explant on a multiple bud inducing media. Rather, Fry refers to a method of regeneration wherein "the regenerable plant tissue is placed in a medium capable of producing shoots from the regenerable tissue" (col. 4, lines 35-39), and then transferred to a second medium capable of producing roots from said shoots (col. 5, lines 22-23). The regeneration of a plurality of buds from ***multiple explants***, as referred to in Fry, is not the

equivalent of regeneration of a plurality of buds from a single explant. As noted in the specification, "the primary meristems give rise to multiple secondary buds, in some cases upwards of one hundred secondary buds per primary meristem" [0051]. This "allows for an increased output without significantly increasing the amount of labor or plant tissue input" [0051]. There is no teaching in Fry of a method involving placing the explant on a media suitable for regeneration of multiple buds from a single primary meristem. Therefore, Fry does not teach all elements of the claimed invention. Thus, no *prima facie* case for anticipation has been set forth.

In view of the foregoing, it is respectfully requested that the rejection be removed.

C. Rejections under 35 U.S.C. § 103

1. Rejection over Zhou *et al.*

The Action has again rejected claims 2-16 under 35 U.S.C. § 103(a) as being unpatentable over Zhou *et al.* (*Plant Cell Reports* 15: 159-163, 1995), in view of Tegeder *et al.* (*Plant Cell Reports* 15: 164-169, 1995), further in view of Weeks *et al.* (*Plant Physiol.* 102: 1007- 1084, 1993), still further in view of *Cheng et al.* (*Plant Physiol.* 115: 971-980, 1997). Applicants traverse as the cited combination of references does not teach or suggest all elements of the instant claims.

As outlined above, the Action has failed to identify any reference that teaches the use of a multiple bud inducing media in a method for transforming wheat. In fact, the Action fails to identify any reference that teaches or suggests the use of a multiple bud-inducing media. For example, the Action asserts that "the Zhou *et al.* reference does teach culturing of explant in a bud inducing media". However, claim 1 of the current invention recites that the explant is to be

cultured "in a first ***multiple*** bud inducing media suitable for inducing production of a plurality of buds from at least one of said meristems" (emphasis added). As noted above, the a multiple bud inducing media "generates multiple plants from a single explant" [0028]. A teaching regarding culturing of an explant in a bud inducing media is not equivalent to producing a plurality of buds from one explant by use of a multiple bud inducing media. The specification notes that this feature "provides a reproducible, efficient method of obtaining transformed plants that is genotype independent and is labor-saving and cost-effective" [0052]. This benefit is not realized if a plurality of buds is not produced by a single explant. The Action also asserts that Tegeder *et al.* teach that media supplemented with cytokinin would result in shoot development; therefore, one of ordinary skill in the art would be motivated to use this teaching to promote shoot development in transformed plants. Again, a media that promotes shoot development is not equivalent to a media that produces a plurality of buds from one explant. The stated object of the invention, "to provide a multiple shoot inducing media to achieve a multiple shooting response from the explants", is not achieved by simply promoting shoot development [0033]. Therefore, there is no teaching or suggestion of the use of a multiple bud inducing media, and the prior art does not teach or suggest all elements of the instant claims. Thus, no *prima facie* case of obviousness has been set forth in the Action.

2. Rejection over Fry *et al.*

The Action also rejects claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Fry *et al.* (U.S. Patent 5,631,152, May 20, 1997), in view of Eudes *et al.* (U.S. Patent 6,995,016, which is a continuation-in-part of application 09/641,243, filed August 17, 2000).

As discussed above, there is no teaching in Fry of a method involving placing the explant on a media suitable for regeneration of multiple buds from a single primary meristem. The

Action asserts that Fry *et al.* teach inducing a plurality of buds because Fry teach the culturing of calli on a modified MS medium consisting of auxin. As noted above, the regeneration of multiple plants from ***multiple explants***, as referred to in Fry, is not the equivalent of regeneration of multiple buds from a ***single explant***.

The Action also states that Eudes *et al.* teach that hormone content of the media is of great significance, and knowing the roles of auxin and cytokinins in plant development would lead one of ordinary skill in the art to understand that bud inducing media would comprise cytokinins and auxins. However, it is not taught or suggested that these media are "suitable for inducing production of a plurality of buds from at least one of said meristems" as recited in claim 1. As emphasized in the specification, in this method "the explants are cultured in a manner so as to produce multiple buds, and when cultured in a multiple shoot inducing media, these buds form shoots that can be grown into mature plants" [0028]. This particular aspect of the claimed invention provides an increase in "the quantity of target cells per explant" [0051], and as noted above this increased quantity allows for "an increased output without significantly increasing the amount of labor or plant tissue input" [0051]. As Fry and Eudes do not teach or suggest a medium for inducing the production of a plurality of buds from a single explant, they do not create a *prima facie* case of obviousness.

3. Surprising and Unexpected Results Establish Non-Obviousness

Applicants further note that none of the references of record teach or suggest the surprising and unexpected results obtained with the methods of the instant invention. In particular, the instant invention provides a method for producing multiple transgenic plants from a single explant by virtue of a multiple bud-inducing media. Such results would not have been expected and could not have been predicted in view of the prior art of record, which only taught

or suggested the production of a single plant from an explant. For example, as shown in Table 3 of the specification (Page 19) the multiple bud inducing media of the invention is able to producing 20-80 buds from a single primary meristem in over 70% of wheat explants. This resulting ability to produce a large number of transgenic plants constitutes both a quantitative difference over the art of record and also a difference in kind in that they enable production of multiple transgenic plants from a single starting explant. As noted above, "the primary meristems give rise to multiple secondary buds, in some cases upwards of one hundred secondary buds per primary meristem" [0051]. This "allows for an increased output without significantly increasing the amount of labor or plant tissue input" [0051]. Overall, the current invention "provides a reproducible, efficient method of obtaining transformed plants that is genotype independent and is labor-saving and cost-effective" [0052]. In addition, the claimed method "is capable of producing plants faster than conventional methods" allowing plants to be "recovered as soon as 8-13 weeks from initiation of the method" [0052]. Thus, methods of the instant invention offer surprising an unexpected advantages relative the prior art, which does not teach multiple bud induction.

Withdrawal of the rejection is thus respectfully requested.

D. Rejection for double patenting

The Action next rejects claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,631,152 (Fry *et al.*). As discussed above, the current application is not made obvious by Fry *et al.* There is no teaching in Fry of a method involving placing the explant on a media suitable for regeneration of multiple buds from a single primary meristem. As noted above, the regeneration of multiple plants from

multiple explants, as referred to in Fry, is not the equivalent of regeneration of multiple buds from a single explant. Additionally, Fry do not teach or suggest the surprising and unexpected results obtained with the methods of the instant invention, namely obtaining multiple transgenic plants from a single explant by virtue of a multiple bud-inducing media. As Fry do not teach or suggest a medium for inducing the production of a plurality of buds from a single explant, the reference does not create a *prima facie* case of obviousness and cannot be the basis for an obviousness-type double patenting rejection.

In light of the foregoing, Applicants respectfully request withdrawal of the rejection.

E. Conclusion

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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